

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. DISPOSITION OF THE CLAIMS**

Claims 7, 11, and 18 are requested to be cancelled.

Claims 1, 4, 5, 13, and 22 are currently being amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-6, 8-10, 12-17, and 19-23 are now pending in this application.

**II. CLAIM OBJECTION**

The claim objection has been obviated by amendment. Claim 1 has been amended to recite “5 x 10<sup>10</sup> and 5 x 10<sup>11</sup> cfu/ml” in conformance with the Office’s interpretation of the replaced term “5.1010 and 5.1011 ufc/ml”.

**III. REJECTIONS UNDER § 112**

The indefiniteness rejections have been obviated by amendment.

Claim 1 has been amended to define the term “more resistant”.

Claims 4-5 have been amended to depend from claim 3 instead of claim 1.

Claim 7 has been canceled. The limitations of claim 7 have been incorporated into claim 1, wherein the phrase “capable of being obtained” has been replaced with “obtained by”.

Claim 13 has been amended to delete “primarily”.

Claim 22 has been amended to replace “the production line” with “a production line”.

#### **IV. NON-OBVIOUSNESS**

The claims stand rejected as obvious over US 2004/0115308 (“Bengtsson-Riveros”) and US 6,306,638 (“Yang”), alone or in combination with several other references.

The additional references applied by the Office include Hayakawa et al., J. Ferm. Bioeng., Vol. 70, No. 6, p. 404-408, 1990 (“Hayakawa”), SCK-CEN 2003, US 2004-0175407 (“McDaniel”), US 3,228,838 (“Rinfret”), and US 2,364,049 (“Bensel”).

Applicants respectfully traverse.

The claims as amended are non-obvious over the cited references because Hayakawa seeks to avoid intermediate treatment steps such as concentrating and drying as presently claimed, and because the cited references nowhere contemplate the problem of loss of bacterial viability during a concentrating treatment.

“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. \_\_, 82 U.S.P.Q.2d 1385, 1391 (2007). Here, the Office cannot meet its burden to provide the required “articulated reasoning with some rational underpinning” with respect to the presently amended claims.

Bengtsson-Riveros concerns the obtention of an edible product containing viable probiotics. Bengtsson-Riveros recalls that probiotics (e.g., lactic acid bacteria) are conventionally used so far in the food industry according to the following process:

- 1- fermentation;
- 2- concentration (e.g., centrifugation or filtration);
- 3- drying; and
- 4- application to a food product.

The method proposed in Bengtsson-Riveros aims at preventing substantial losses of CFUs between fermentation and application to the food product (viability is essentially reduced upon drying). To do so, Bengtsson-Riveros provides the following method:

- 1- fermentation until a relatively high concentration of probiotics is obtained;
- 2- very optionally (and not preferably), concentration (e.g., centrifugation or filtration); and
- 3- application of the resulting liquid to a food product (“directly and freshly”).

In all examples, protective agents are added to the probiotics before step 3 (see Tables 3,6,8, 10, 12, and 15, in agreement with [0028]).

Yang relates to native or mutants bifidobacteria strains having tolerance in the gastrointestinal environment, i.e., tolerance to bile salt, acid and oxygen. These bacteria show excellent growth in skim milk, no other growth-promoting substances being needed. Yang discloses assays to screen for tolerance (*inter alia*, acid tolerance, see column 8, lines 26-36).

Hayakawa aims at providing an efficient culture method for *Lactobacillus casei* to obtain cells in high density. Hayakawa discloses a cross-flow filtration system featuring a sintered carbon membrane having a 0.141  $\mu\text{m}$  porosity, such a system avoiding any undesirable membrane plugging.

Hayakawa also improved the culture method by increasing the feed rate of fresh medium according to the cellular growth, so that a final concentration of 40g/L ( $10^{11}$  cfu/ml) can be reached more rapidly and using a reduced fresh medium volume.

SCK-CEN 2003 proposes to measure several bacterial physical (size, shape, etc.) and biochemical (proteins, DNA, RNA, etc.) characteristics by flow cytometry in order to monitor the physiological status of bacteria under stress conditions.

The purpose of Bengtsson-Riveros is to avoid any intermediate treatment (such as concentrating and drying) between the steps of producing a bacterial biomass by fermentation in a liquid medium and applying it to a food product (see [0023]). This is the reason why D1

indicates "preferably, the fermentation is continued until a relatively high concentration of cfu is obtained" (in [0025]) and stresses on the "direct application of the fresh biomass to the edible product.

The cited references nowhere contemplate the problem posed by the loss of bacterial viability during a concentrating treatment. This is a clear concern, even when using tangential filtration, as reflected in Crespo et al. (Chemical Engineering Science, 1992, 47: 205-214; cited in the International Search Report and in the IDS as filed on December 1, 2006, as citation No. A3).

By failing to recognize this problem, the cited references cannot be considered to lead a skilled artisan to the present invention as claimed. The present invention addresses this unrecognized problem.

Claim 3 further distinguishes the cited references by specifying survival rate at certain conditions and "pH between 3 and 7". In rejecting claim 3, the Office relies on Table 16 in Bengtsson-Riveros, wherein bacterial viability is assessed during storage of a "junior cereal product onto liquid probiotic biomass was applied. Table 16 shows there is no loss of viability for at least 90 days at 20°C.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." M.P.E.P. § 2143.03, quoting *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970).

Here, claim 3 is non-obvious because Bengtsson-Riveros and Yang do not satisfy the claim 3 limitation "pH between 3 and 7". The Office alleges that "it is well known in the art that cereals have a pH between 5 and 6" (see Office Action, page 5). Table 1 in Bengtsson-Riveros discloses the composition of the "junior cereal product" used in Table 16. The "junior cereal product" corresponds to extruded cereal rings with sugar/honey coating, composed of cereals (wheat, oats and barley), sugar, honey, maltodextrin, vitamins and minerals (density of 115 g/L).

Applicants dispute the Office's allegation concerning the "well-known" pH of cereal products based on the following. As confirmed by the Wikipedia website, which is cited only for illustrating the common general knowledge, pH is defined as a measure of the acidity or basicity of a solution. It is calculated as the co-logarithm of the acidity of dissolved hydrogen ions ( $H^+$ ) (see <http://en.wikipedia.org/wiki/PH>).

Here, the cereal product of Table 16 in Bengtsson-Riveros is not a solution. It is a dry product, as it can also be deduced from the water activity ( $Aw$  below 0.1). Therefore, the cereal product disclosed in Table 16 of Bengtsson-Riveros cannot have any pH.

To the extent that the Office relies on inherency, it is well-established that inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." M.P.E.P. § 2163.07(a) (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2002) (quoting *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599 (Fed. Cir. 2002) and *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

The cereal product has a pH only after it is reconstituted with water, but this is not relevant for the storage conditions illustrated in Table 16.

### **CONCLUSION**

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a

check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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